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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,661	04/29/2002	Lian-Hui Zhang	2577-127	5708

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,661	ZHANG ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-14,16 and 18-25* is/are pending in the application.

4a) Of the above claim(s) *6,14,16,18 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7,9-13 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1, 3-7, 9-14, 16 and 18-25 are pending.

2. This application contains claims 6, 14, 16, 18 and 22-25 drawn to an invention nonelected with traverse in the response filed 11 August 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

3. The title of the invention is not descriptive of the instant invention. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long. In the response filed 7 February 2005 Applicant urges that the title has been amended. This is not found persuasive because the claims are drawn to nucleic acid not proteins.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 1, 3-5, 7, 9-13 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 November 2005. Applicant's arguments filed 7 February 2005 have been fully considered but they are not persuasive.

Applicant urges that the invention is described using the terms "nucleic acids", "sequence", "hybridize" and "coding portions", which are well known in the art (response pg 10).

This is not found persuasive because the terms "nucleic acids", "sequence", "hybridize" and "coding portions" do not describe the structural features of the claimed nucleic acids.

Applicant urges that given the well-known base complementarity one would discern a multitude of sequences with the scope of claim 1(c) (response pg 10-11).

This is not found persuasive because the structural and functional features of the claimed nucleic acids are not described. A nucleic acid that hybridizes to another may have only a small region in common and may encode a protein with a very different function.

Applicant urges that the specification describes the invention as providing a new strategy for engineering resistance to disease, that this invention would be applicable to other proteins whether they are AiiA homologs or not, and that the specification describes techniques to extent the invention beyond the specific AiiA protein (response pg 10-11).

This is not found persuasive. The specification does not describe non-AiiA proteins at all.

Applicant urges that the function of the nucleic acid of claim 1(c) is to hybridize to any nucleic acid encoding SEQ ID NO:2 and this molecule can then be used to confer bacterial resistance in plants or animals (response pg 11-12).

This is not found persuasive because not all nucleic acids that hybridize to any nucleic acid encoding SEQ ID NO:2 would encode a AiiA protein. The specification does to describe the structural features that distinguish nucleic acids that hybridize to any nucleic acid encoding SEQ ID NO:2 and that encode AiiA proteins from those that hybridize to any nucleic acid encoding SEQ ID NO:2 and that do not encode AiiA proteins.

Applicant urges that signal peptide coding regions are well-known in the art, and that the specification discloses on pg 9 that the nucleic acid may optionally comprise a signal peptide coding regions; it is fundamental biology that these regions are about 20 amino acids and mark a peptide for secretion, citing a textbook (response pg 12).

This is not found persuasive because the specification does not describe any such regions that function in plants. The textbook could not considered because it was not sent.

Applicant urges that pg 10-11 of the specification describes membrane attachment regions as something that can be incorporated into the peptide sequence of AiiA for anchoring the AiiA enzyme in the outer surface of plant cell membranes (response pg 12-13).

This is not found persuasive because those words do not describe the structure (in this case, the sequence) of membrane attachment regions.

Applicant urges that donor organisms, including 240B1, are disclosed on pg 15 of the specification (response pg 13).

This is not found persuasive because without deposit of bacterial isolate 240B1, "bacterial isolate 240B1" are simply words. The structural and functional features of that isolate and others that function as donor organisms are not described.

6. Claims 1, 3-5, 7, 9-13, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding SEQ ID NO:2, does not reasonably provide enablement for nucleic acids that hybridize to SEQ ID NO:1 or that hybridize to any nucleic acid that encodes SEQ ID NO:2, vectors comprising them, cells transformed with the vector and a method of using the nucleic acids to increase disease resistance in a plant. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 November 2005. Applicant's arguments filed 7 February 2005 have been fully considered but they are not persuasive.

Applicant urges that one of skill in the art knows that hybridization is a process where the nucleic acid base pairs with a complimentary sequence, and that hybridizations can be set up to only occur between highly homologous nucleic acids (response pg 15-16).

This is not found persuasive because the sequence of such nucleic acid is not taught, nor are the organisms from which such nucleic acids may be found taught.

Applicant urges that a website has formula that calculates that the minimum homology of the DNA target to the probe is greater than 79% (response pg 16).

This is not found persuasive. The website could not considered because it was not sent. The formula as presented in the response seems to use a specific GC percent for the DNA molecule. However claim1(c) is drawn to any nucleic acid that hybridizes to any nucleic acid that encodes SEQ ID NO:2. The vast majority of nucleic acids that encode SEQ ID NO:2 will not be 37% GC. Furthermore, the neither the claim nor the specification teach the necessary and sufficient structural elements of nucleic acids that hybridize to nucleic acids that encode SEQ ID NO:2 and encode an AiiA protein. And it does not teach how to use nucleic acids that hybridize to nucleic acids that encode SEQ ID NO:2 and encode do not an AiiA protein. It is noted that the formula does not take the length of the DNA molecule into account. A nucleic acid that hybridizes to another may have only a small region in common and may encode a protein with a very different function.

Applicant urges that E. coli promoters have certain features and a promoter could be identified using well know molecular biological techniques (response pg 17-18).

This is not found persuasive. E. coli promoters will not function in plants. The specification does not teach under which promoters the nucleic acid that hybridizes to SEQ ID NO:1 or that hybridizes to any nucleic acid that encodes SEQ ID NO:2 must be expressed from in plants to provide disease resistance.

Applicant urges that it would not be undue experimentation to screen through nucleic acid that hybridize to a nucleic acid that encodes SEQ ID NO:2, and the specification identified plants with increased disease resistance (response pg 18-19).

This is not found persuasive. The specification teaches no plants transformed with a nucleic acid that hybridizes to any nucleic acid encoding SEQ ID NO:2. Making all possible single amino acid substitutions in an 250 amino acid long protein like that encoded by SEQ ID NO:1 would require making and analyzing 19^{250} nucleic acids; the protein would have 99.6% homology to SEQ ID NO:2. Because nucleic acids that hybridize to SEQ ID NO:1 or that hybridize to any nucleic acid that encodes SEQ ID NO:2 would encode proteins with many amino acid substitutions, many more than 19^{250} nucleic acids would need to be made and analyzed. Because of the number of possible nucleic acids and because of the lack of guidance in the specification as to which ones to analyze, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with increased disease resistance, if such plants are even obtainable.

Lastly, there is reason to suspect that nucleic acids encoding SEQ ID NO :2 would not confer resistance ion a plant. Molina et al (2003, FEMS Microbiol. Ecol. 45:71-81) teach that application of lactonase-expressing bacterial strains eliminated the effectiveness of disease-suppressing bacteria, resulting in diseased plants (paragraph spanning the columns, pg 78). Zhang (2003, Trends Plant Sci. 8:238-244) teach that transformation of plants with another nucleic acid that encodes an enzyme that controls lactone levels resulted in disease resistant plants in one case, but more susceptible plants in the other, and suggest that these results mean fine-tuning is required to match host-pathogen combinations (paragraph spanning the columns, pg 242).

Applicant urges that the sequence with accession number AF196486 is available from GenBank and certain references, though it need not be made publically available due to its disclose in the publication; it would not be undue experimentation to isolate a nucleic acid that hybridizes to any nucleic acid that encodes SEQ ID NO:2 because 240B1 is publically available. Applicant also urges that one could use standard molecular biological techniques and a computer to screen soil isolates for acyl homoserine degrading activity (response pg 20).

This is not found persuasive. GenBank does not have organisms in it and does not make organisms available. Accession number AF196486 would be a sequence; a sequence is not an organism.

The specification does not teach from which organisms the nucleic acid of claim 1, part (c) can be isolated, or which organisms can be used as donor organisms in the method of claims 19-21. Additionally, as bacterial isolate 240B1 is not deposited or publicly available, it cannot even be used to isolate the nucleic acid of SEQ ID NO:1.

7. Claims 1, 3-5 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 November 2005. Applicant's arguments filed 7 February 2005 have been fully considered but they are not persuasive.

Claim 1 is indefinite in its recitation of "the coding portion of SEQ ID NO:1" in part (a). Any nucleic acid has at least 6 potential reading frames, and thus at least 6 coding portions. It is unclear to which the claim refers.

Applicant urges that one of skill in the art would understand the scope of the claim in light of the specification, and the coding portion is shown in Figure 4A as starting at base 1 (response pg 20).

This is not found persuasive. Limitations in the specification are not to be read into the claim. It is suggested that the claim be amended to recite the specific base range of SEQ ID NO:1 that Applicant wishes to claim.

Conclusion

8. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

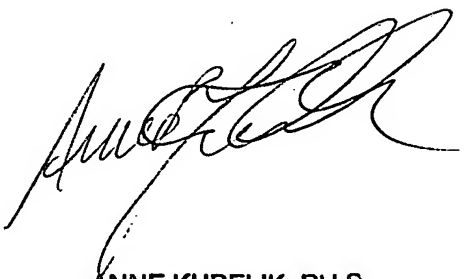
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
May 12, 2005



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER